CLAIMS

What is claimed is:

1. A sterilized polymeric material for use in a body of a mammal wherein said polymeric material is sterilized by irradiation at a temperature below 25 °C.

2. The sterilized polymeric material of claim 1 which further comprises a therapeutically active agent.

3. The sterilized polymeric material of claim 1 wherein said temperature is at or below about 5 °C.

4. The sterilized polymeric material of claim 2 which comprises polymeric microspheres, microparticles, microcapsules, or implants.

5. The sterilized polymeric material of claim 2 which comprises polymeric microspheres, microparticles, or microcapsules.

6. The sterilized polymeric material of claim 5 which comprises polymeric microparticles.

7. The sterilized polymeric material of claim 5 which comprises polylactide-co-glycolide or polylactic acid.

8. The sterilized polymeric material of claim 5 which comprises polylactide-co-glycolide.

9. The sterilized polymeric material of claim 5 wherein said temperature is below about 15 °C.

10. The sterilized polymeric material of claim 5 wherein said temperature is below about 10 °C.

11. The sterilized polymeric material of claim 5 wherein said composition temperature is at or below about 5 °C.

12. The sterilized polymeric material of claim 5 which is sterilized by gamma irradiation at a dose of about 1.5 to about 4.0 mRad.

13. The sterilized polymeric material of claim 5 wherein said therapeutically active agent comprises a retinoid, a prostaglandin, a tyrosine kinase inhibitor, a glucocorticoid, an androgenic steroid, an estrogenic steroid, a

non-estrogenic steroid, an intracellular adhesion molecule inhibitor or an alpha-2-adrenergic agonist.

14. The sterilized polymeric material of claim 5 wherein said therapeutically active agent comprises a retinoid.

15. The sterilized polymeric material of claim 5 wherein said therapeutically active agent comprises tazarotene.

16. A method of sustained delivery of a therapeutically active agent to a mammal comprising administering a sterilized polymeric material comprising said therapeutically active agent to said mammal, wherein the polymeric material is sterilized by irradiation at a temperature below 25 °C.

17. The method of claim 16 wherein the sterilization by irradiation comprises gamma irradiation.

18. The method of claim 17 wherein said temperature is below about 15 °C.

19. The method of claim 17 wherein said temperature is below about 10 °C.

20. The method of claim 17 wherein said temperature is below about 5 °C.

21. The method of claim 17 wherein said temperature is from -25°C to 5 °C.

22. A method of sterilizing a polymeric material for use in a body of a mammal comprising irradiating said polymeric material at a temperature below 25 °C.

23. The method of claim 22 wherein the polymeric material further comprises a therapeutically active agent.

24. The method of claim 22 wherein said temperature is below about 15 °C.

25. The method of claim 22 wherein said temperature is below about 10 °C.

26. The method of claim 22 wherein said temperature is below about 5 °C.

27. A composition comprising sterilized polymeric microparticles and a therapeutically active agent for use in a body of a mammal wherein said polymeric material is sterilized by irradiation with external cooling of said polymeric material during sterilization.

28. The composition of claim 27 wherein said composition is suitable for sustained delivery of said therapeutically active agent.

29. The composition of claim 27 wherein the temperature of said polymeric material at the end of the sterilization process is about 10 °C to about 50 °C lower than said temperature would be in the absence of external cooling.

30. The composition of claim 27 wherein the temperature of said polymeric material at the end of the sterilization process is about 20 °C to about 50 °C lower than said temperature would be in the absence of external cooling.

31. The composition of claim 27 wherein the temperature of said polymeric material at the end of the sterilization process is about 50 °C or more lower than said temperature would be in the absence of external cooling.

32. A method of sterilizing a polymeric material for use in a body of a mammal comprising irradiating said polymeric material with external cooling of the polymeric material.

33. The method of claim 32 wherein the temperature of said polymeric material at the end of the sterilization process is about 10 °C to about 50 °C lower than said temperature would be in the absence of external cooling.

34. The method of claim 32 wherein the temperature of said polymeric material at the end of the sterilization process is about 20 °C to about 50 °C lower than said temperature would be in the absence of external cooling.

35. The method of claim 32 wherein the temperature of said polymeric material at the end of the sterilization process is about 50 °C or more lower than said temperature would be in the absence of external cooling.

36. The method of claim 16 wherein the polymeric material comprises polylactide-co-glycolide or polylactic acid.

37. The method of claim 16 wherein the polymeric material comprises polylactide-co-glycolide.

38. The composition of claim 27 wherein the polymeric material comprises polylactide-co-glycolide or polylactic acid.

39. The composition of claim 27 wherein the polymeric material comprises polylactide-co-glycolide.